CHAPTER 237

GOVERNMENT - STATE

SENATE BILL 14-155

BY SENATOR(S) Steadman, Hodge, Lambert, Aguilar, Crowder, Guzman, Heath, Kefalas, Kerr, Newell, Nicholson, Todd; also REPRESENTATIVE(S) May and Duran, Gerou, Exum, Ginal, Hamner, Hullinghorst, Kagan, Kraft-Tharp, Labuda, McCann, Melton, Mitsch Bush, Moreno, Pettersen, Primavera, Rosenthal, Ryden, Schafer, Singer, Williams, Young.

AN ACT

CONCERNING GRANT FUNDING FOR MEDICAL MARIJUANA HEALTH EFFECTS STUDIES.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly finds and declares that:

- (a) Over 100,000 Coloradans currently use medical marijuana for relief from constitutionally authorized debilitating medical conditions that do not respond to conventional treatments;
- (b) More information is needed to further understand potential therapeutic uses of marijuana and its component parts. Research on the therapeutic effects of marijuana and its component parts could benefit thousands of Coloradans who suffer from additional debilitating medical conditions that do not respond to conventional treatments and are not currently permissible medical conditions for medical marijuana use.
- (c) The purpose of the medical marijuana program cash fund is to establish, operate, and maintain the medical marijuana program. The state health agency considers proposals to include additional debilitating medical conditions to the list of conditions for which a person may use medical marijuana in the medical marijuana program as a part of its operational duties for the medical marijuana program cash fund.
- (d) The state health agency needs additional medical research on the potential therapeutic benefits of marijuana and its component parts to:

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

- (I) Add new debilitating medical conditions to Colorado's medical marijuana law; and
- (II) Help physicians better understand the biochemical effects of prescribed medical marijuana;
- (e) Other state-funded medical marijuana research programs have advanced the scientific knowledge about how marijuana works and methods to ensure appropriate dosing. Colorado can now advance that knowledge further;
- (f) Colorado can conduct observational trials that have the possibility of leading to clinical trials with changes from the federal government; and
- (g) Colorado is a national leader in the development of new strains of marijuana and its component parts that appear to have promising therapeutic effects.
- (2) Therefore, the general assembly finds it is appropriate to establish the health research subaccount in the medical marijuana program fund to fund medical marijuana health research.

SECTION 2. In Colorado Revised Statutes, 25-1.5-106, amend (17) as follows:

- 25-1.5-106. Medical marijuana program powers and duties of state health agency rules medical review board medical marijuana program cash fund subaccount created repeal. (17) Cash fund. (a) The medical marijuana program cash fund shall be subject to annual appropriation by the general assembly to the state health agency for the purpose of establishing, operating, and maintaining the medical marijuana program. All moneys credited to the medical marijuana program cash fund and all interest derived from the deposit of such moneys that are not expended during the fiscal year shall be retained in the fund for future use and shall not be credited or transferred to the general fund or any other fund.
- (b) (Deleted by amendment, L. 2010, (HB 10-1284), ch. 355, p. 1677, \S 2, effective July 1, 2010.)
- (b.5) Notwithstanding any provision of paragraph (a) of this subsection (17) to the contrary, on June 30, 2011, the state treasurer shall deduct three million dollars from the medical marijuana program eash fund and transfer such sum to the general fund.
 - (c) Repealed.
- (d) (I) There is created a health research subaccount, referred to as "subaccount" in this section, in the medical marijuana program cash fund. The subaccount is established to support funding for medical marijuana health research. The department shall have continuous spending authority over the subaccount. The department may direct the state treasurer to transfer money from the medical marijuana program cash fund to the subaccount based on the cost of health research projects approved by the state board of health pursuant to section 25-1.5-106.5. The state treasurer shall not transfer more than ten million dollars in

TOTAL TO THE SUBACCOUNT.

- (II) For the 2014-15 fiscal year and each fiscal year through 2018-19, the alternative target reserve for purposes of section 24-75-402 for the medical marijuana program cash fund will be sixteen and five-tenths percent of the amount in the fund, excluding the ten million dollars available for transfer to the subaccount and any amount in the subaccount.
- (III) This paragraph (d) is repealed, effective July 1, 2019. Any money remaining in the subaccount on June 30, 2019, must revert to the medical marijuana program cash fund.
- (e) Notwithstanding any provision of paragraph (a) of this subsection (17) to the contrary, on July 1, 2014, and each July 1 through 2018, the state treasurer shall transfer two hundred thousand dollars from ten million dollars available for transfer pursuant to paragraph (d) of this subsection (17) in the medical marijuana program cash fund to the subaccount to be used for administrative purposes to administer the medical marijuana health research grant program created pursuant to section 25-1.5-106.5.

SECTION 3. In Colorado Revised Statutes, **add** 25-1.5-106.5 as follows:

- **25-1.5-106.5.** Medical marijuana health research grant program. (1) Legislative intent. There is a need for objective scientific research regarding the efficacy of marijuana and its component parts as part of medical treatment. It is the intent of the general assembly that the department gather objective scientific research regarding the efficacy of administering marijuana and its component parts as part of medical treatment.
- (2) **Medical marijuana research grant program rules.** (a) (I) The department shall be responsible for the administration of the Colorado medical marijuana research grant program created within the department and referred to in this section as the "grant program".
- (II) THE DEPARTMENT SHALL COORDINATE THE GRANT PROGRAM TO FUND RESEARCH INTENDED TO ASCERTAIN THE GENERAL MEDICAL EFFICACY AND APPROPRIATE ADMINISTRATION OF MARIJUANA AND ITS COMPONENT PARTS. THE GRANT PROGRAM SHALL BE LIMITED TO PROVIDING FOR OBJECTIVE SCIENTIFIC RESEARCH TO ASCERTAIN THE EFFICACY OF MARIJUANA AND ITS COMPONENT PARTS AS PART OF MEDICAL TREATMENT AND SHOULD NOT BE CONSTRUED AS ENCOURAGING OR SANCTIONING THE SOCIAL OR RECREATIONAL USE OF MARIJUANA. THE GRANT PROGRAM SHALL FUND OBSERVATIONAL TRIALS AND CLINICAL TRIALS.
- (b) THE STATE BOARD OF HEALTH SHALL PROMULGATE RULES FOR THE ADMINISTRATION OF THE GRANT PROGRAM, INCLUDING:
- (I) The procedures and timelines by which an entity may apply for program grants;

- (II) Grant application contents, including:
- (A) Descriptions of Key Personnel, including clinicians, scientists, or epidemiologists and support personnel, demonstrating they are adequately trained to conduct this research;
- (B) PROCEDURES FOR OUTREACH TO PATIENTS WITH VARIOUS MEDICAL CONDITIONS WHO MAY BE SUITABLE PARTICIPANTS IN RESEARCH ON MARIJUANA AND ITS COMPONENT PARTS;
- (C) PROTOCOLS SUITABLE FOR RESEARCH ON MARIJUANA AND ITS COMPONENT PARTS AS MEDICAL TREATMENT;
- (D) FOR ANY RESEARCH STUDIES, DEMONSTRATION THAT APPROPRIATE PROTOCOLS FOR ADEQUATE PATIENT CONSENT AND FOLLOW-UP PROCEDURES ARE IN PLACE; AND
- (E) A PROCESS FOR A GRANT RESEARCH PROPOSAL APPROVED BY THE GRANT PROGRAM TO BE REVIEWED AND APPROVED BY AN INSTITUTIONAL REVIEW BOARD THAT IS ABLE TO APPROVE, MONITOR, AND REVIEW BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS;
- (III) CRITERIA FOR SELECTING ENTITIES TO RECEIVE GRANTS AND DETERMINING THE AMOUNT AND DURATION OF THE GRANTS, WHICH SHALL INCLUDE THE FOLLOWING:
- (A) The scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome; and
- (B) The researchers' expertise in the scientific substance and methods of the proposed research and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research; and
- (IV) REPORTING REQUIREMENTS FOR ENTITIES THAT RECEIVE GRANTS PURSUANT TO THIS SECTION.
- (c) Program grants will be paid from the health research subaccount in the medical marijuana program cash fund created in section 25-1.5-106 (17).
 - (d) IN ORDER TO MAXIMIZE THE SCOPE AND SIZE OF THE MARIJUANA STUDIES:
- (I) The grant program may solicit, apply for, and accept moneys from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the marijuana studies that are authorized under this section; except that the program shall not accept any moneys that are offered with any conditions other than that the moneys be used to study the efficacy of marijuana and its component parts as part of medical treatment; and

- (II) All donors shall be advised that moneys given for purposes of this section will be used to study both the possible medical benefits and detriments of marijuana and its component parts and that he or she will have no control over the use of these moneys.
- (3) Review of applications. (a) (I) Scientific advisory council. IN ORDER TO ENSURE OBJECTIVITY IN EVALUATING RESEARCH PROPOSALS, THE GRANT PROGRAM SHALL ESTABLISH A SCIENTIFIC ADVISORY COUNCIL, REFERRED TO IN THIS SECTION AS THE "COUNCIL", TO PROVIDE A PEER REVIEW PROCESS THAT GUARDS AGAINST FUNDING RESEARCH THAT IS BIASED IN FAVOR OF OR AGAINST PARTICULAR OUTCOMES. THE EXECUTIVE DIRECTOR OF THE DEPARTMENT SHALL APPOINT AT LEAST SIX MEMBERS AND NO MORE THAN THIRTEEN MEMBERS TO THE COUNCIL TO PROVIDE POLICY GUIDANCE IN THE CREATION AND IMPLEMENTATION OF THE GRANT PROGRAM AND IN SCIENTIFIC OVERSIGHT AND REVIEW. THE CHIEF MEDICAL OFFICER OF THE DEPARTMENT, OR HIS OR HER DESIGNEE, IS ALSO A MEMBER OF THE COUNCIL AND IS CHAIR OF THE COUNCIL. EXCEPT FOR THE REPRESENTATIVE SPECIFIED IN SUB-SUBPARAGRAPH (L) OF THIS SUBPARAGRAPH (I), THE EXECUTIVE DIRECTOR SHALL CHOOSE MEMBERS ON THE BASIS OF THEIR EXPERTISE IN THE SCIENTIFIC SUBSTANCE AND METHODS OF THE PROPOSED RESEARCH AND FOR THEIR LACK OF BIAS OR CONFLICT OF INTEREST REGARDING THE APPLICANTS OR THE TOPIC OF AN APPROACH TAKEN IN THE PROPOSED RESEARCH AND MAY CHOOSE MEMBERS FROM AROUND THE COUNTRY. MEMBERS OF THE COUNCIL MUST INCLUDE THE FOLLOWING TYPES OF EXPERTS:
- (A) AT LEAST ONE EPIDEMIOLOGIST WITH EXPERTISE IN DESIGNING AND CONDUCTING LARGE, OBSERVATIONAL STUDIES AND CLINICAL TRIALS;
- (B) AT LEAST ONE CLINICIAN WITH EXPERTISE IN DESIGNING AND CONDUCTING CLINICAL TRIALS;
- (C) A CLINICIAN FAMILIAR WITH THE PRESCRIPTION, DOSAGE, AND ADMINISTRATION OF MEDICAL MARIJUANA UNDER CURRENT STATE LAWS;
 - (D) A MEDICAL TOXICOLOGIST;
 - (E) A NEUROLOGIST;
 - (F) A PEDIATRICIAN;
 - (G) A PSYCHIATRIST;
- (H) An internal medicine physician or other specialist in adult medicine;
 - (I) A PREVENTIVE MEDICINE SPECIALIST OR PUBLIC HEALTH PROFESSIONAL;
 - (J) A SUBSTANCE ABUSE SPECIALIST;
- (K) An alternative medicine specialist with expertise in Herbal or alternative medicine;

- (L) A PERSON WHO REPRESENTS MEDICAL MARIJUANA PATIENT INTERESTS; AND
- (M) AN AD HOC MEMBER WITH CLINICAL EXPERTISE IN THE MEDICAL CONDITION UNDER STUDY.
- (II) MEMBERS OF THE COUNCIL, OTHER THAN THE CHIEF MEDICAL OFFICER OR HIS OR HER DESIGNEE, SHALL SERVE ON A VOLUNTARY BASIS FOR A TWO-YEAR TERM AND MAY BE REAPPOINTED. MEMBERS SHALL BE REIMBURSED FOR THEIR TRAVEL EXPENSES INCURRED IN THE COURSE OF THEIR PARTICIPATION.
- (III) MEMBERS OF THE COUNCIL SHALL EVALUATE RESEARCH PROPOSALS AND SUBMIT RECOMMENDATIONS TO THE DEPARTMENT AND THE STATE BOARD OF HEALTH FOR RECOMMENDED GRANT RECIPIENTS, GRANT AMOUNTS, AND GRANT DURATION.
- (b) **Grant approval.** (I) The council shall submit recommendations for grants to the state board of health. The state board of health shall approve or disapprove of grants submitted by the council. If the state board of health disapproves a recommendation, the council may submit a replacement recommendation within thirty days.
- (II) The state board of health shall award grants to the selected entities, specifying the amount and duration of the award. A grant awarded pursuant to this section shall not exceed three years without renewal. The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available grant program funding.
- (4) **Reporting.** (a) No later than January 1, 2016, the grant program shall report to the state board of health on the progress of the medical marijuana studies.
- (b) Thereafter, the grant program shall issue a report to the state board of health by January 1 of each year detailing the progress of the medical marijuana studies. The interim reports required under this paragraph (b) shall include data on all of the following:
 - (I) THE NAMES AND NUMBER OF DISEASES OR CONDITIONS UNDER STUDY;
 - (II) THE NUMBER OF PATIENTS ENROLLED IN EACH STUDY BY DISEASE; AND
 - (III) ANY SCIENTIFICALLY VALID PRELIMINARY FINDINGS.
- (5) Cultivation authority. The attorney general shall seek authority from the federal government to permit Colorado institutions of higher education to contract with the national institute of drug abuse to cultivate marijuana and its component parts for use in research studies funded pursuant to this section.
- (6) **Definition.** For purposes of this section, "marijuana" means "usable form of marijuana" as that term is defined in section 14(1)(i) of article

XVIII of the Colorado constitution and also includes "industrial Hemp" as that term is defined in section 16 (2) (d) of article XVIII of the Colorado constitution.

SECTION 4. In Colorado Revised Statutes, 24-75-402, **add** (5) (dd) as follows:

- **24-75-402.** Cash funds limit on uncommitted reserves reduction in amount of fees exclusions repeal. (5) Notwithstanding any provision of this section to the contrary, the following cash funds are excluded from the limitations specified in this section:
- (dd) The medical marijuana program cash fund, but only with respect to the portion of the fund transferred to or available for transfer to the health research subaccount created in section 25-1.5-106 (17) (d), C.R.S.

SECTION 5. Effective date. This act takes effect July 1, 2014.

SECTION 6. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.

Approved: May 21, 2014